USSN 10/662,493 CT2752NP

Remarks

Status of the claims. Claims 1-59 are pending. Claims 1, 43, 45, and 46 were rejected under 35 USC 112, first paragraph. Claims 1 and 43 were rejected under 35 USC 112, second paragraph. Claims 1-10 and 16-34 were provisionally rejected under 35 USC 101 for statutory double patenting. Claims 54 and 59 were provisionally rejected under judicially created double patenting.

Amendments to claims. Claims 1 and 54 were amended to delete terms where N(A¹-R¹)(A²-R²) defined heteroaromatic ring systems. Claim 56 was amended to delete "substance abuse" and "post-traumatic stress syndrome."

Rejection under 35 USC 112, first paragraph. The examiner rejected claims 1, 43, 45, and 46, arguing that the claim term for "A¹-R¹ and A²-R² forming rings" were not enabled throughout the scope of the term. The examiner pointed out that the specification disclosed pyrrolidine as the only example for this claim term. The applicants respectfully traverse.

First, while amended claims 1 and 54 still encompass certain heteroalicyclic ring systems, the amended claims delete terms where $N(A^1-R^1)(A^2-R^2)$ defined heteroaromatic ring systems.

Second, "the test of enablement is whether one reasonably skilled in the art could make and use the invention from the disclosure in the patent coupled with information known in the art without undue experimentation." *U.S. v. Telectronics* 857 F.2d 778 (Fed. Cir. 1988). "A patent need not teach, and preferably omits, what is well known in the art." *In re Buchner* 929 F.2d 660 (Fed. Cir. 1991). Furthermore, the scope of the enablement must only bear a "reasonable correlation" to the scope of the claims. *In re Fisher* 427 F.2d 833 (CCPA, 1970).

Mattson et al. (WO 02/079152, published October 10, 2002) discloses an analogous series of cyclopropylmethyl amines which demonstrate SSRI activity (see structures below). This series of compounds discloses a variety of heteroalicyclic amines which correspond to cyclic N(A¹-R¹)(A²-R²) moleties. The examples include rings of different sizes, rings with additional heteroatoms, and bicyclic rings. Pyrrolldine is exemplified in this series (examples 46, 84, 124, 145, 166, 172, 179, and 185) as well as piperidine (examples 33, 34, 47, 73, 85, and 140), piperazine (examples 35, 36, 74, and 75), morpholine (examples 137 and 141), and tetrahydroisoquinoline (examples 37 and 76).

USSN 10/662,493 CT2752NP

Because of the direct correlation of the pyrrolidine analogs, those skilled in the art would reasonably predict that all of the heteroalicyclics disclosed in Mattson, as well as other close analogs, would demonstrate SSRI activity. Thus, there is a "reasonable correlation" of enablement to the claim scope of $N(A^1-R^1)(A^2-R^2)$, and the large amount of guidance in the specification and in the art teaches those skilled in the art to practice the entire scope of the claim term $N(A^1-R^1)(A^2-R^2)$ without undue experimentation.

Regarding claims 43, 45, and 46, these claims do not specifically encompass compounds where A¹-R¹ and A²-R² form rings. The applicants respectfully request the examiner to clarify or withdraw the enablement rejection directed to these claims.

The applicants believe the basis for the rejection based on enablement for "A1-R1 and A2-R2 forming rings" has been removed and respectfully request the examiner to withdraw the rejection.

The examiner also rejected claim 56 as not being enabled for "substance abuse" or "post-traumatic stress disorder."

Claim 56 was amended to delete the terms for "substance abuse" and "post-traumatic stress disorder." The applicants believe the basis for this rejection has now been removed and respectfully request the examiner to withdraw this enablement rejection.

Rejection under 35 USC 112, second paragraph. The examiner rejected claim 1 and all depending claims as being indefinite for "N" being "bonded to 4 substituents," arguing that valency does not permit 4 bonds to nitrogen. The applicants respectfully traverse.

An amine can be bonded to 4 substituents, as in the case of quarternary salts and N-oxides. Mattson discloses such a salt as example 187 (see structure below). The current claim terms where N is bonded to 4 substituents relate to such quarternary compounds.

USSN 10/662,493 CT2752NP

The examiner also rejected claims 1 and 43 for "unclear scope" in reciting "what was excluded rather than defining what was invented." The applicants respectfully traverse.

Regarding claim 1, the examiner cited *In re Schecter*, but misconstrued the facts in that case. In *Schecter*, the applicant claimed an "alkenyl radical other than 2-butenyl and 2,4-pentadienyl." This claim term was indefinite because the scope of alkenyls was unlimited and included an infinite number of alkenyls, known and unknown, except for the two prior art compounds. More recent cases have endorsed negative limitations if there is nothing "inherently ambiguous or uncertain about the limitation" (MPEP 2173.05(i)).

Claim 1 unambiguously defines the scope of the Invention and then qualifies certain elements within the defined scope. Negative limitations within a defined claim scope is an acceptable practice and is not a basis for an indefiniteness rejection.

Claim 43 does not recite a negative limitation and the applicants request the examiner to clarify or withdraw the rejection directed to indefiniteness for this claim.

The applicants believe there is no basis for rejections based on indefiniteness and respectfully request the examiner to withdraw these rejections.

Rejection under 35 USC 101. The examiner provisionally rejected claims 1-10 and 16-34 for claiming the same invention as copending U.S. application 10/662,745. The applicants respectfully traverse.

The test for statutory double patenting is whether the same invention is being claimed twice, where the "same invention" means identical subject matter. *Miller v. Eagle Mfg.* 151 U.S. 186 (1984).

The current application claims compounds which are substituted in a 1,2 sense while application no. 10/662,745 claims compounds in a 1,3-sense.

$$A_{1}$$
 A_{3}
 A_{1}
 A_{3}
 A_{1}
 A_{1}
 A_{1}
 A_{1}
 A_{1}
 A_{1}
 A_{1}
 A_{2}
 A_{3}
 A_{1}
 A_{2}
 A_{3}
 A_{1}
 A_{2}
 A_{3}
 A_{1}
 A_{2}
 A_{3}
 A_{3}
 A_{1}
 A_{2}
 A_{3}
 A_{3}
 A_{4}
 A_{5}
 A_{5

USSN 10/662.493

CT2752NP

As the subject matter in these applications is not identical, the applicants respectfully request the examiner withdraw the rejection based on statutory double patenting,

Rejection under judicially created double patenting. The examiner provisionally rejected claims 54 and 59 for obviousness-type double patenting over claims 43 and 48 copending U.S. application 10/662,745. The applicants traverse.

Judicially created double patenting is to prevent improper extension of a patent term and may be overcome by filing terminal disclaimers.

While the applicants do not concede that the inventions claimed in the two applications are patentably indistinct, the rejection is unwarranted because the two applications were filed on the same day and there is no patent term to disclaim. The applicants respectfully request the examiner to withdraw the rejection based on obviousness-type double patenting.

The applicants believe the application is now in allowable form and respectfully request favorable reconsideration. If any issues remain regarding the allowance of this application, the Examiner is respectfully invited to contact the applicants' agent, James Epperson, by phone (203-677-6974), fax (203-677-6900), or e-mail (james,epperson@bms.com).

Respectfully submitted,

Date:

Bristol-Myers Squibb Company

Patent Department

P.O. Box 4000 Princeton, NJ 08543-4000 James Epperson Agent for Applicants Reg. No. 52,867

Phone: (203) 677-6974